

K243253 6600 Ultrasound System (MyLabA50)Jun 18, 2025
246 days to decisionK243253 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k243253/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Oct 15, 2024 |
| Decision date | Jun 18, 2025 |
| Days to decision | 246 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | 6600 Ultrasound System (MyLabA70) |

APPLICANT

| | |
|----------------|---|
| Company | Esaote, S.P.A. |
| Location | Genoa, IT |
| Contact | Piet De Jong |
| Website | https://www.esaote.com |
| 510(k) history | 67 submissions · 67 cleared · 2003-2026 |

Esaote, S.P.A. is a medical diagnostic imaging company based in Genoa, Italy. The company specializes in ultrasound, MRI, and healthcare IT solutions for clinical settings. Esaote has received FDA 510(k) clearances from total submissions since 2003. The company's regulatory portfolio is dominated by Radiology devices, representing 100% of its FDA submissions. Recent cleared devices include the MyLab ultrasound systems and Magnifico Open imaging platforms. The company remains actively engaged in FDA regulatory submissions, with the latest clearance in 2026. Esaote's produc...